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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,417	03/30/2004	Po-Ying Chan-Hui	131.03US	5640

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H. THOMAS ANDERTON, JR.
345 OYSTER POINT BLVD
SOUTH SAN FRANSISCO, CA 94080

EXAMINER	
PHAM, AUDREY S	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,417	CHAN-HUI ET AL.	
	Examiner	Art Unit	
	Audrey S. Pham	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Chan-Hui *et al.*

Claims 1-45 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 24-45 drawn to a method of determining disease status of a patient suffering from a disease characterized by aberrant expression of one ErbB cell surface receptor complex, wherein the disease is cancer, comprising measuring directly in a patient sample an amount of one ErbB cell surface receptor complex, comparing each amount to its corresponding amount in a reference sample, and correlating differences in the amounts from the patient sample and the respective corresponding amounts from the reference sample to the disease status of the patient., classified in class 435, subclass 7.23.

II. Claims 1, 8-12, 30, 40-42, 44, drawn to a method of determining disease status of a patient suffering from a disease characterized by aberrant expression of one ErbB cell surface receptor complex, wherein the disease is aberrant fibrotic condition, comprising measuring directly in a patient sample an amount of each cell surface receptor complex, comparing each amount to its corresponding amount in a reference sample, and correlating differences in the amounts from the patient sample and the respective corresponding amounts from the reference sample to the disease status of the patient., classified in class 435, subclass 4.

III. Claims 16-23 drawn to a method of selecting a patient for treatment of cancer with one ErbB-dimer acting drug, comprising the steps of isolating a patient sample containing cancer cells from a patient, measuring directly in the patient sample an amount of one cell surface receptor dimers, comparing each amount

to its corresponding amount from a reference sample and selecting the patient for treatment with one dimer-acting drugs, classified in class 435, subclass 7.23.

The inventions are distinct, each from the other for the following reasons:

The inventions of groups I-III are materially distinct methods, which differ at least in objectives, method steps and reagents. Specifically, group I is a prognosis method drawn to determining a disease status in cancer patients whereas group II is drawn to a method of determining a disease status in a patient population suspected or has aberrant fibrotic condition. Group III is a screening method drawn to selecting a patient for treatment of cancer with a dimmer-acting drug. Each group also differs in the reagents and steps they use to accomplish the various objectives. For example, group I uses a cell surface receptor (e.g., Her1-Her1 complex) that the invention of group II does not use. Searching all of the groups with all of the different reagents, steps or objectives would invoke a high burden of search because the searches would not be coextensive.

These inventions are distinct for the reasons given above and they have acquired separate statuses in the art as shown by their different classifications. The search required for one group is not required for the other groups and vice versa. For these reasons, restriction for examination purposes as indicated is proper.

Applicant is reminded that the reply to this requirement to be completed must include an election of the invention to be examined even though the requirement be traversed (See 37 CFR 1.143).

Species Election

One or more of the invention groups above contain multiple generic claims that include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility. Because they are not so

closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Groups I-III (Claims 2, 5, 10, 17, 25, 27, 31, 38, 40) are generic to a plurality of disclosed patentably distinct species comprising the following patient samples: fixed tissues sample, frozen tissue sample and circulating epithelial cells. The above species represent separate and distinct patient samples that differ at least in etiology, pathology, and mechanisms such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group I (Claims 3, 9, 14, 19-21, 24, 34-36 and 44) is generic to a plurality of disclosed patentably distinct species comprising the following ErbB cell surface receptors: Her1-Her1 homodimers, Her2-Her2 homodimers, Her1-Her3 receptor dimers, Her2-Her4 receptor dimers, Her1-PI3K complexes, Her2-PI3K complexes, Her3-PI3K complexes, Her1-SHC complexes, Her2-SHC complexes, Her3-SHC complexes, Her1-IGF-1R receptor dimers, Her2-IGF-1R receptor dimers, Her3-IGF-1R receptor dimers, Her1-PDGFR receptor dimers, Her2-PDGFR receptor dimers, Her3-PDGFR receptor dimers, p95Her2-Her3 receptor dimers, p95Her2-Her2 receptor dimers, p95Her2-Her1 receptor dimers, EGFRvIII-Her1 receptor dimers, EGFRvIII-Her2 receptor dimers, and EGFRvIII-Her3 receptor dimmers, Her1-Her3, Her1-Her4, Her2-Her2, Her3-Her4, and Her4-Her4, Her1-Her2. The above species represent separate and distinct complexes with different function and structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group II (Claims 9 and 44) is generic to a plurality of disclosed patentably distinct species comprising the following ErbB cell surface receptors: Her1-PDGFR receptor dimers, Her2-PDGFR receptor dimers, and Her3-PDGFR receptor dimmers, Her1-PI3K complexes, Her2-PI3K complexes, Her3-PI3K complexes, Her1-SHC complexes, Her2-SHC complexes, Her3-SHC complexes, IGF-1R-PI3K complexes, IGF-1R-SHC complexes, PDGFR-PI3K complexes, and PDGFR-SHC complexes. The above species represent separate and distinct complexes with different function and structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group III (Claims 19-21) is generic to a plurality of disclosed patentably distinct species comprising the following ErbB cell surface receptors: Her1-Her1, Her1-Her2, Her1-Her3, Her1-Her4, Her1-Her1, Her1-Her3, Her1-Her4. The above species represent separate and distinct complexes with different function and structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Groups I-II (Claims 7, 13, 29, 33, 37, 43) are generic to a plurality of disclosed patentably distinct species comprising the following cancers: breast, ovarian, prostate, colorectal and glioblastoma. The above species represent separate and distinct cancer with different etiology, pathology, and mechanisms such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group III (Claims 18, 22) is generic to a plurality of disclosed patentably distinct species comprising the following dimer-acting drugs: Cetuximab (Erbitux), Trastuzumab (Herceptin), h-R3 (TheraCIM), ABX-EGF, MDX-447, ZD-1839 (Iressa), OIS-774 (Tarceva), PKI 166, GW574016, CI-1033, EKB-569, and EMD 72000. The above species represent separate and distinct drugs that differ at least in structure and function such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Upon election of any one group, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species that corresponds with the elected receptor group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventorship Amendment

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended to be in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request, as set forth in 37 CFR 1.48(b), and by a processing fee, as set forth in 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Audrey S. Pham
Patent Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER